INTEROFFICE COMMUNICATION

WASHINGTON STATE PATROL

TO: Lieutenant Rob Sharpe, Impaired Driving Section

FROM: Sergeant Ken Denton, Impaired Driving Section

SUBJECT: Draeger Alcotest 9510 Testing

DATE: December 27, 2013

Prior to deployment of the new evidential breath testing instrument in the field, validation of the instruments was conducted to ensure the fitness for purpose. The testing was completed in the Spring of 2013 and follow up testing completed in the Fall of 2013. This report is intended to serve as the conclusion for the testing.

All instruments tested and included in this report were Draeger Alcotest 9510 series. They may be referred to in this report simply as Draeger(s), 9510(s), or any combination of the name listed above.

In April 2013 technicians from the Breath Test Program (BTP) were brought together at the Forensic Laboratory Services Bureau headquarters in Seattle. Instructions were provided for the technicians and tasks were divided between the different technicians. The testing was completed over a three day period and the results were produced within the "Draeger 9510 Validation Testing" document.

Much of the testing that was completed involved the completion of accuracy (bias or systematic error) and precision (coefficient of variation) percentage values. The Breath Test Program has long used parameters within its calibration/quality assurance procedure (QAP) of +/- 5% for bias and less than or equal to 3% for precision. When the BTP looked to the National Highway Traffic Safety Administrations (NHTSA) Federal Register for guidance, it was discovered that the recommended test standards were limited to only four test solutions (0.02, 0.40, 0.08, and 0.16). The guidelines used a systematic error of ≤ 0.005 BAC compared to the reference value of the solution for the 0.02, 0.04, and 0.08 and a ≤ 0.008 for the 0.16 value. The precision recommendation only looked at a standard deviation of ≤ 0.0042. For the purposes of this testing the BTP used a combination of the model guidelines from NHTSA as well as the current accuracy and precision criteria used in the BTP. The BTP criteria has been in use for over 25 years.

Level of Detection and Quantification:

Brief Summary:

- Completed on four separate Draeger instruments
- Tested using four different alcohol simulator solutions ranging from 0.01 g/210L – 0.03 g/210L

- Examined results for Accuracy/Bias of +/- 5% or +/- 0.005 g/210L difference between the mean result and reference values
- Examined results of Precision/ Coefficient of Variation (CV) of less than 3% or 0.0042 standard deviation
- Five samples of each solution and the deionized water was completed

Conclusion: The four instruments that were tested produced values that were within the criteria established for acceptability listed above. There was no single series of test that exceeded a 0.0016 g/210L difference when compared to the reference value provided for each solution. Based on these tests, the Draeger instruments are capable of accurately and precisely detecting and quantifying ethanol at levels as low as 0.010 g/210L.

Accuracy & Precision/ Measurement Range:

Brief Summary:

- Completed on two separate Draeger instruments
- Tested using 13 different alcohol simulator solutions ranging from 0.02 g/210L – 0.60 g/210L
- Examined results for Accuracy/Bias of +/- 5% or +/- 0.005 g/210L difference between the mean result and reference values
- Examined results of Precision/ Coefficient of Variation (CV) of less than 3% or 0.0042 standard deviation
- Five samples of each solution were completed

Conclusion: All results were examined and with the exception of one outlier met the criteria required for accuracy and precision. The outlier occurred on April 23, 2013 on instrument serial number ARAH-0098. The solution that failed to meet the criteria was batch number T00002. The results from this batch produced a standard deviation higher than 0.0042 and the bias levels were higher than 3%. This was the only value and instrument to produce these numbers. The following two days the same instrument and same solution tested well within the above parameters. The outlier data appears to be related to a warm up and or equilibration period based on the follow up testing.

The rest of the data produced favorable numbers and are capable of accurately and precisely measuring ethanol levels ranging from 0.02 g/210L to 0.60 g/210L.

Based on the outlier and the equilibration, the calibration procedure within the Breath Test Program Technical Manual will identify the importance of equilibration of the simulators prior to introducing the vapor to the instrument whenever running tests related to the calibration (Quality Assurance Procedure).

Robustness & Ruggedness:

Brief Summary:

- Testing consisted of varying ambient air temperature and air pressure.
  - Ambient Air Temperature Testing
    - Normal laboratory temperature conditions
    - Lower than normal laboratory temperature conditions
    - Higher than normal laboratory temperature conditions
    - Each temperature condition used two different instruments
    - Each instrument tested three simulator solutions with values of 0.04, 0.08, 0.15 g/210L, and one dry gas standard with value of 0.08 g/210L. Each solution or gas standard was sampled five times under the conditions.
    - Testing completed on two instruments
  - Ambient Pressure Testing
    - Completed on two instruments
    - Completed using dry ethanol gas
    - Tests performed at or near sea level
    - Tests performed at higher elevation/ different pressure conditions

Normal Laboratory Temperature Conditions:

This test was conducted in temperatures which are consistent with normal laboratory environmental condition. The measured temperature was between 70-72.9 degrees Fahrenheit. Both instruments yielded accurate and precise results for each of the solution values as well as the dry gas standard.

Below Normal and Above Normal Laboratory Conditions:

Below normal temperature testing was conducted in temperatures which would not normally be seen in a laboratory environment. The measured temperature for these tests ranged from 57.9-61.1 degrees Fahrenheit. Accuracy levels and some precision levels were not met on either instrument during this testing for simulator solutions. This is to be expected as the cold temperatures prohibit the headspace of the simulator as well as tubing from maintaining an equilibrated temperature, therefore decreasing the vapor molecules introduced to the Draeger for testing. The dry gas standards remained constant throughout the testing, despite the temperature differential. This is also to be expected, as the dry gas is not dependent upon temperature.

Likewise, when testing was done at above normal lab temperatures, ranging from 77.0-82.6 degrees Fahrenheit, similar results were obtained. Some of the accuracy and precision levels did not fall within permitted values. However, as with the low temperature testing, the dry gas produced values very similar to those seen in normal temperature conditions.

Conclusion: Simulator solutions will not be utilized for field evidential testing by the Draeger instruments. The solutions will be utilized for calibration/Quality Assurance Procedures (QAP) purposes. Current BTP Technical Manual procedures already identify laboratory conditions and states:

- *"When the QAP is undertaken at sites other than a permanent laboratory facility, the location should provide moderate environmental conditions of temperature and humidity as commonly found under normal laboratory conditions. Calibration shall be stopped if the Technician determines that environmental conditions in any calibration location jeopardize the results of the calibration."*

The importance of ensuring normal laboratory conditions is evident as a result of this testing and the importance of the environmental conditions will be emphasized in all manuals as well as all future technician training.

Ambient Pressure Conditions

The Draeger instruments contain an internal barometer which tracks changes in ambient air pressure conditions. This is important as the dry gas standards used as an external standard on the instruments are pressurized tanks. A change in the ambient air pressure could change the results of any measured value unless the pressure change is recognized and accounted for in the sampling of the gas vapor. A reference barometer was used and the value was compared to the pressure reading obtained from the Draeger instruments. The manufacturer recommends that the pressure reading from Draeger instrument be within +/- 10 mbar of the pressure reading from the reference barometer. This was conducted for each instrument at each location tested. Five samples of the dry gas were conducted at the FLSB headquarters and the instruments were then driven to Snoqualmie Pass (Hyak DOT facility). Even though the pressure readings from the two different locations were nearly 90 mbar difference, there was little change in the reading of the dry gas values.

Conclusion: The pressure compensation mechanism contained within the Draeger instruments can reliably report ethanol vapor of gas standards when ambient air pressure changes. Procedures for checking the internal barometer located within the Draeger instrument have been developed and placed into the BTP Technical Manual.

Interfering Substance Testing:

Brief Summary:

- Testing was on three Draeger instruments
- Tested for acetone, isopropyl, and methanol
- Tested water then added each substance and recorded reading
    - Test for each substance done independently
- Readings were recorded on preprinted document

Deionized water and substances identified above were obtained from the state toxicology laboratory. The water was poured into a simulator and warmed to appropriate temperature. The water was tested and values recorded. 0.15mL of acetone was added to the water and then sampled by the instrument. The Draeger instruments determine interfering substances using a comparison of the infrared detector and the electrochemical (EC) readings. If a difference of 0.008 g/210L or 10% is noted, the instrument will produce the interference message.

When testing acetone, two of the three instruments did not detect acetone until 2.1mL had been added to the water. The third instrument did not read it at all.

Testing of isopropyl yielded results on two of three instruments of "Invalid Sample" and "Samples Outside of 10%". The third instrument did detect interference after .300mL was added to the water.

Methanol testing yielded interfering substance detection on two of three instruments once a .150mL had been added to the water. The third instrument yielded results of "Invalid Sample" when .150mL was added to the water and then interference detected during a second attempt of the same value.

Each of the interfering substance tests were of concern as this was not what the expected results would contain in some cases. After discussion with the manufacturer representatives, it was explained that the instrument algorithm for detection of interfering substances was designed to not report the interference unless at least one of the ethanol values was at least a preset value. There were other factors related to sampling parameters that caused the other error messages of "Invalid Sample" and "Samples Outside of 10%". After the validation testing was completed, the BTP requested that the manufacturer change the algorithm for interfering substances. A letter was provided by the manufacturer to the BTP along with a software update on June 4, 2013. The letter explained the former settings and confirmed that no analytical ethanol detection mechanism was changed within the software during the upgrade.

Once the software upgrade was completed, it was installed on one instrument that was calibrated using the approved method for calibration and the interference tests were completed again. This time the tests did start with a solution ethanol concentration of 0.01 g/210L as a baseline rather than the water. The results yielded the interfering substance error message and were recorded in the overall plan at that time.

Conclusion: Once the software was understood and corrective measures were put into place, the Draeger instrument reads interfering substances as expected, and can be reasonably expected to do so, on each instrument after upgrades have occurred.

Carryover Testing:

Brief Summary:

- Tests were performed using two Draeger instruments
- Deionized water was used as a test standard
- Two simulator solutions were also utilized in testing with values of 0.30 & 0.50 g/210L
- Tests of the simulator solutions were followed by tests of water to ensure no contamination would carry to the next sample taken

Carryover tests were completed by attaching a simulator with an alcohol simulator to the Draeger instrument. The solution was sampled by the instrument, then detached from the instrument and a simulator filled with deionized water was attached to the instrument and sampled. This was repeated for a total of three times on each of the solution values of 0.30 g/210L and then 0.50 g/210L.

Each of the instruments performed well and none of the high concentration of ethanol solutions had any carryover effect on the tests of water which followed.

Conclusion: The Draeger instruments are capable of purging the sample chamber of contaminating ethanol prior to accepting the next sample without carryover.

Testing completed in Fall 2013

After examining the data from the testing reported to this point, it was decided to tests more instruments using a series of ten samples rather than five as was done in the Spring. Ten separate Draeger instruments were calibrated using approved protocol. After the calibration was completed, a series of nine solution values were sampled by the instruments ranging from 0.010-0.040 g/210L. These tests were repeated five times on five separate days and the values were examined for accuracy and precision.

The following data is also found within the Validation Testing Document:

The following pages of this summary include accuracy and/or precision comparison charts for each instrument. The charts only include the highest single day value for each solution that was tested over five days. For accuracy/bias, this number can be either positive or negative. The number chosen from the data was the largest found from the five days of testing on each solution.

The typical data trends found were that a bias percentage of +/- 5% and precision percentage of ≤ 3% were more difficult to obtain at lower concentrations (0.04 and lower). However, when comparing the mean to the reference values, these were never outside of the ≤0.005 criteria. Similarly, some of the higher concentrations were found to be outside of the ≤0.005 or ≤0.008 criteria, but almost always met the +/- 5% criteria. The exceptions are the four instruments below. Each of these instruments failed to meet either of criteria (+/-5% bias and a difference greater than 0.005 g/210L). Those details are documented below.

ACCURACY

- **ARAH-0084** did not meet either bias or systematic error criteria as described below:
    - Batch D00006, the EC was outside of both criteria on day 1 only
        - -7.29% bias (difference of -0.0111) day 1
    - Batch D00007, the EC was outside of both criteria on days 4 & 5

    - -5.48% bias (difference of -0.0111) day 4
    - -5.19% bias (difference of -0.0105) day 5

  - Batch D0008, the EC was outside of both criteria on days 4 & 5
    - -7.06% bias (difference of -0.0215) day 4
    - -6.14% bias (difference of -0.0187) day 5

  - Batch D00009, the EC was outside of both criteria on days 2, 4, & 5
    - -5.32% bias (difference of -0.0214) day 2
    - -6.81% bias (difference of -0.0274) day 4
    - -7.25% bias (difference of -0.0292) day 5

- **ARAH-0094** did not meet either bias or systematic error criteria as described below:

  - Batch D00007, the EC was outside of both criteria on days 2, 4, & 5
    - -5.73% bias (difference of -0.0116) day 2
    - -6.27% bias (difference of -0.0127) day 4
    - -5.68% bias (difference of -0.0115) day 5

  - Batch D00009, the EC was outside of both criteria on day 5 only
    - -5.12% bias (difference of -0.0206) day 5

- **ARAH-0103** did not meet either bias or systematic error criteria as described below:
  - Batch D00008, the EC was outside of criteria on day 5 only
    - -5.95% bias (difference of -0.0181) day 5

  - Batch D00009, the EC was outside of criteria on days 3 & 5
    - -5.59% bias (difference of -0.0225) day 3
    - -5.12% bias (difference of -0.0206) day 4

- **ARAH-0107** did not meet either bias or systematic error criteria as described below:

  - Batch D00005, the EC was outside of both criteria on days 2, 3, 4, & 5
    - -7.21% bias (difference of -0.0058) day 2
    - -7.09% bias (difference of -0.0057) day 3
    - -6.59% bias (difference of -0.0053) day 4
    - -7.71% bias (difference of -0.0063) day 5

  - Batch D00006, the EC was outside of both criteria on days 2, 3, 4, & 5

    - -6.64% bias (difference of -0.0101) day 2
    - -6.11% bias (difference of -0.0093) day 3
    - -6.31% bias (difference of -0.0096) day 4
    - -7.16% bias (difference of -0.0109) day 5

- Batch D00007, the EC was outside of both criteria on days 1, 2, 3, 4, & 5
    - -5.24% bias (difference of -0.0106) day 1
    - -5.09% bias (difference of -0.0103) day 2
    - -6.08% bias (difference of -0.0123) day 3
    - -5.63% bias (difference of -0.0114) day 4
    - -8.40% bias (difference of -0.0170) day 5

- Batch D00008, the EC was outside of both criteria on days 1, 2, 3, 4, & 5
    - -6.31% bias (difference of -0.0192) day 1
    - -6.24% bias (difference of -0.0190) day 2
    - -7.95% bias (difference of -0.0242) day 3
    - -7.82% bias (difference of -0.0238) day 4
    - -10.22% bias (difference of -0.0311) day 5

- Batch D00009, the EC was outside of both criteria on days 1, 2, 3, 4, & 5
    - -6.98% bias (difference of -0.0281) day 1
    - -6.46% bias (difference of -0.0260) day 2
    - -8.07% bias (difference of -0.0325) day 3
    - -8.94% bias (difference of -0.0360) day 4
    - -9.44% bias (difference of -0.0380) day 5

Note that all of the four above instruments that were unable to obtain accuracy either by a bias percentage or a difference in values only had these on the electrochemical (EC or fuel cell sensor). In the scenarios above, none of the above instruments produced bias percentages and/or difference values that were outside of tolerance on both the infrared and electrochemical sensors. In discussions with the manufacturer, some fuel cells will fatigue faster than others. The higher the alcohol volumes that these fuel cells are subjected to on a repeated basis (back to back, as done in this testing) it becomes more likely to see fuel cell fatigue and values as demonstrated in the four instruments above. This is quite often remedied with replacement of a fuel cell and recalibration of the instrument.

In addition, when examining each of the above instruments that had these accuracy readings outside of tolerances it is easily seen from the data that when a fuel cell is experiencing fatigue, it begins to read ethanol lower than expected, not higher. When relating to a subject breath sample, the error is always in favor of the subject, not penalizing by causing higher than expected readings. Also, the instrument has built in safeguards to prevent a valid test from occurring when the IR value is more than 0.008 g/210L difference from the EC value or a difference of greater than 10% in the IR versus EC values (whichever is higher). This is the mechanism to screen for interfering substances. These interferences will not be detected when the instrument is in the Supervisory Test mode as was utilized in this testing. However, if a breath sample is being analyzed, and the criteria for interfering substances is not met, the test would be aborted and an error logged in the instrument memory.

Conclusion: The data that was produced did yield some results outside of the accuracy criteria on some of the instruments, some of the time. However, these results were all found on the EC value and not the IR value as stated above. In addition, when the values were outside of stated parameters, the values were low, or reading below what was expected. It can be reasonably assumed that this would be the case for evidential tests as well which means that the EC values would be in the favor of a subject as opposed to falsely elevating their BrAC.

There was only one instance of not meeting precision criteria and it appears to be an isolated series of tests.

FINAL CONCLUSION:

Based upon all findings within the validation testing completed, the Draeger Alcotest 9510 is fit for the purpose for which it is designed. It is recommended that the instrument proceed to the next phase for deployment.

KLD:kld

I HAVE REVIEWED AND APPROVED THE VALIDATION MATERIALS. I FIND THAT THE INSTRUMENT IS FIT FOR PURPOSE. FORWARD TO MR. ERIK NEILSON, STANDARDS AND ACCOUNTABILITY SECTION, FOR REVIEW.

R SHARPE 1-7-14

I HAVE REVIEWED & APPROVE THE VALIDATION DATA & FIND THE INSTRUMENTS FIT FOR PURPOSE. FORWARDED TO DR. FIONA COUPER FOR HER REVIEW.

2/7/14

Received from Erik Neilson.

2-7-14

Validation material reviewed & approved; data & calculations reviewed & verified. Agree with final conclusions. 3-31-14